

THE NEW FACE of Glucometer®

# Ascensia *ELITE XL*

Diabetes Care System

## USER GUIDE



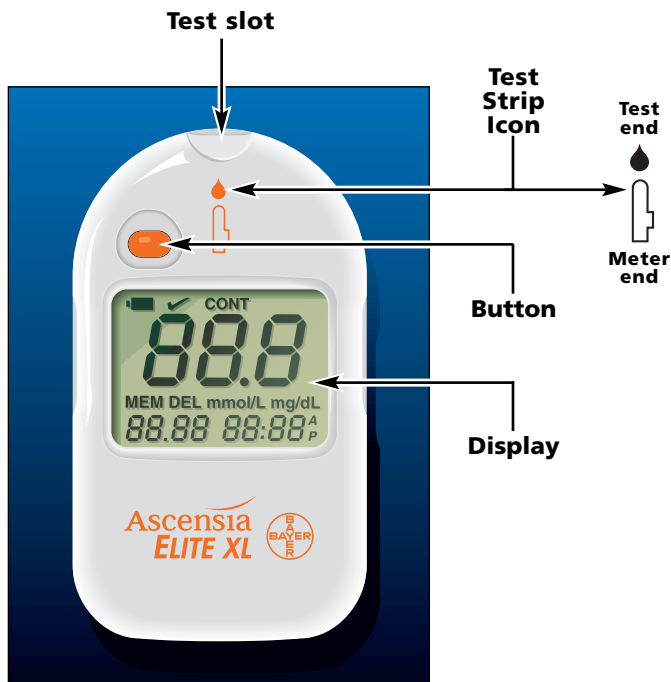
For Use With  
Ascensia *ELITE*™ *XL*  
Blood Glucose Meter

Need Help with Reimbursement?  
Call Our Bayer Care Help Line: 1-877-787-1912

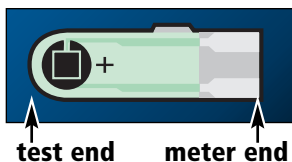
Bayer



# The Meter



## Testing Materials



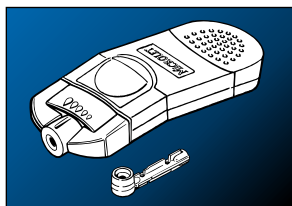
- **Ascensia *ELITE*™ Test Strip** – use for blood or control testing. Insert into Meter before drawing in blood or control sample.



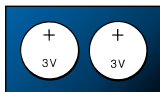
- **Ascensia *ELITE*™ Check Strip** – use to check if the Meter is working properly before running a blood glucose test.



- **Ascensia *ELITE*™ Code Strip** – use to set the Meter (calibrate) to match the box of Test Strips.



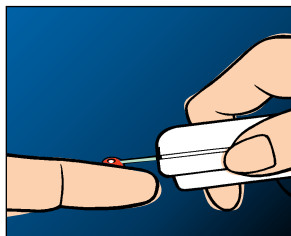
- **MICROLET® Adjustable Lancing Device** – use for finger puncture with a MICROLET® Lancet.



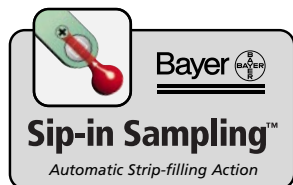
- **NORMAL CONTROL SOLUTION** – use to confirm system is working correctly.
- **BATTERIES** – replace when necessary.

## The Ascensia *ELITE*<sup>™</sup> XL Diabetes Care System is a blood glucose monitoring system for diabetes management in home or professional use.

The system is based on electrode sensor technology. Convenient features of the system are:



- Two-step testing process:
  1. Insert Test Strip in Meter
  2. Touch TEST END to blood
- Test results are displayed in 30 seconds.
- Meter turns on when inserting a strip and turns off when removing the strip.
- Up to 120 test results may be stored in the Meter and can be recalled when necessary.
- Stored results may be transferred to a computer and analyzed with WinGlucofacts<sup>™</sup> XL software.
- Agrees with laboratory serum/plasma glucose results (values 10–15% higher than whole blood glucose results).
- Capillary action at the end of the Test Strip automatically draws a small amount of blood into the reaction chamber.



## Frequently Asked Questions

### **What do I do first?**

If needed, install batteries and set the time—test the Meter electronics with a Check Strip—code the Meter to match Ascensia *ELITE* Test Strips—and then run a control test to test the whole system before running a blood glucose test.

### **What does blood glucose monitoring do for me?**

Blood glucose levels change during the day due to medication, exercise, diet, insulins or hypoglycemics (oral agents) or possibly stress and illness. Blood glucose testing provides information that will help you understand the changes. This information can help you manage your diabetes to keep your blood sugar levels within your target range.

### **Do I need to read this book?**

This instruction guide is provided as a reference as you operate the system. *It is important for you to read through the User Guide to understand how the whole system operates and what information is available for your needs.*

For short simple instructions, a quick reference guide is also provided for your convenience with procedures and information most often needed. It can be useful when traveling.

**If you have any concerns or questions as you learn how to use the system, please call our Customer Service Dept. 1-800-348-8100 or visit our website at [www.ascensia.com](http://www.ascensia.com) or [www.bayercaresdiabetes.com](http://www.bayercaresdiabetes.com)**


## Important Information

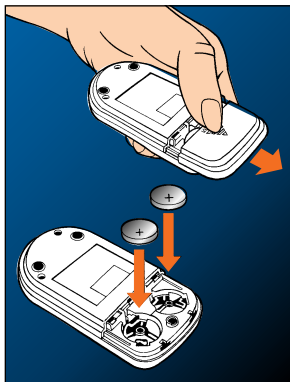
- The Ascensia *ELITE*<sup>™</sup> XL Blood Glucose Meter has been designed for use with Ascensia *ELITE*<sup>™</sup> Test Strips. The performance characteristics of the Meter may not be valid for any other brand of Test Strips. The use of other Test Strips may cause erroneous results. Bayer Corporation does not warrant the use of the Ascensia *ELITE* XL Blood Glucose Meter with any Test Strip other than Ascensia *ELITE* Test Strips.
- Glucose levels below 50 or above 250 mg/dL (below 2.8 or above 13.9 mmol/L) may indicate a potentially serious medical condition. If your glucose is below 50 mg/dL or above 250 mg/dL, contact your healthcare professional immediately.

**CAUTION:** Before using any product to test your blood glucose (sugar), read all instructions and practice the test. Do all quality control checks as directed and consult with a diabetes health professional. These recommendations apply to all blood glucose monitoring systems and are supported by the American Association of Diabetes Educators,\* the American Diabetes Association, the Food and Drug Administration and Health Industry Manufacturers Association.

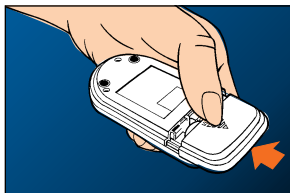
\*You may call the American Association of Diabetes Educators for the location of a Certified Diabetes Educator (CDE) near you 1-800-338-DMED.

| <b>SECTION</b> |                                      | <b>PAGE</b> |
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**Install batteries when the Meter is new if needed. Replace batteries when the Meter displays the battery symbol .**



1. Press firmly on "open" arrow and slide forward in the direction of the arrow. The lid releases.
2. Place new batteries into the battery compartment with the "+" side up. Slide lid back into place, lining up with open slots, and close firmly. Test results stored in the memory are not erased when batteries are changed, but time must be reset.



**NOTE:** Two 3 volt (CR2032) lithium batteries are furnished with the Meter.

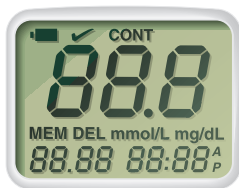
**WARNING: Keep batteries away from children. Lithium batteries are poisonous. If swallowed, immediately contact your physician or poison control center.**

**Discard batteries according to your local environmental regulations.**



## Set the Alarm, Time and Units

**Some Meter options may need to be reset when the Meter is new and when batteries are changed. The options may be changed any time to fit your needs.**



### How do I set the Meter?

Hold the button for five seconds to place Meter in "set up" mode. Press the button to change item as it flashes (you have five seconds to make a change).

**Display 1.** Press button to **switch:** Beeper **on** to beeper **off** if you wish to turn off the sound.

**Display 2.** Press button to **set:**

- Minute
- Hour\*
- Day
- Month
- Year

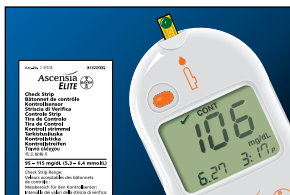
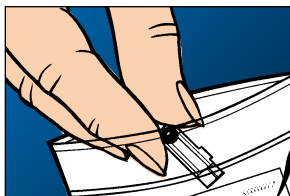
**Display 3.** Press button to **format** (preset at factory to match country):

- Clock (12- or 24-hour day)
- Date (day/month or month/day)
- Units (mg/dL or mmol/L)

Meter returns to full display and turns off automatically.

\*Note am (A) or pm (P) if clock is formatted for a 12-hour day.

**Check your Meter when new or any time after use, to make sure that electronics are working properly.**



## HOW:

1. Remove the Check Strip from the package (save the package).
2. Insert the Check Strip ("check" side up) fully into the Meter until you hear a beep. A full display\* shows, followed by another beep and then the Check Strip result.
3. The Check Strip result must be within the range listed on the Check Strip package insert. If not, see the problem solving chart in Section 11.
4. At the end of the test, carefully remove the Check Strip from the Meter and return it to its package.

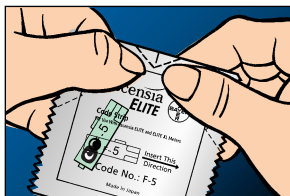
**\*A full display, as shown here, indicates that all characters are working. If ever all the display segments do not appear, see Section 11.**

**Code the Meter whenever a new box of Test Strips is opened.\* This will match the Meter to the Test Strip reactivity.**



## HOW:

You will need the Code Strip found in the new box of strips.



1. Tear open the packet found in the new carton of Test Strips and remove the Code Strip (save the packet).



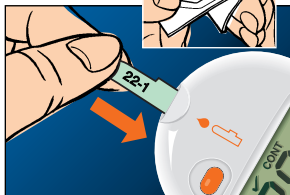
2. Insert the Code Strip into the test slot as shown. A beep sounds and a full display appears briefly. Another beep sounds and the Code Number (for example F-5) appears in the display.



3. Remove the Code Strip and store in packet.

**\*You do not need to code the Meter if the new Code Strip number matches the previous Code Strip number.**

A Control Test is run to find out if the ***whole*** system is working correctly (Test Strip and Meter) ***and*** to practice good technique before blood glucose testing.

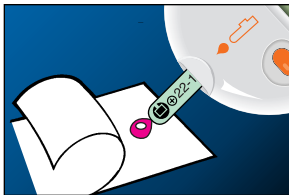
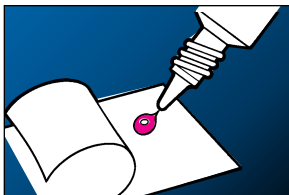


## Prepare for the Test:

1. To open the Test Strip foil packet, carefully peel the foil back until the Test Strip is completely exposed (as shown). Save the foil packet.

**Note:** Numbers printed on each Test Strip are manufacturing numbers and are not to be confused with Code Numbers (F#).

2. Holding the round end of the Test Strip, insert the strip into the Meter until it stops.
3. A beep sounds. A full display, followed by the Code Number (F#) and previous test result, appears. The Code Number and previous test result flash alternately.
4. To mark a Control Test, pull the Test Strip out and reinsert quickly (within 2 seconds). When the "C-" and Code Number (F#) begin flashing, you know the test will be marked.



## Take the Test:

5. Squeeze a small drop of Control Solution onto the inside of the foil packet you saved.
6. Touch and hold the TEST END of the Test Strip to the drop until the Meter beeps (the Control Solution has now been drawn into the Test Strip). The timer begins to count down from 29 seconds.

The test result appears with "CONT" in the display (if marked) when the countdown is complete. Compare result to range on end flap of Test Strip carton.

7. If you did not mark control in #4 or want to delete the test result, see page 10—if you did mark and do not want to delete, record the test result/date in your Clinilog Diary.
8. Remove the Test Strip. The Meter turns off and the result is stored as a Control.

If you did not mark your control or want to delete the test result, do one of the following options before removing the strip. Remember, after marking or deleting, the test result will *then* not be a part of the blood glucose test average and will be stored in the memory and displayed with “CONT” or “DEL”.



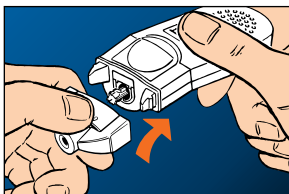
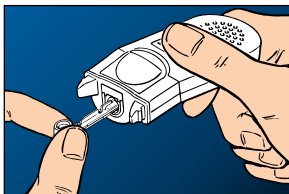
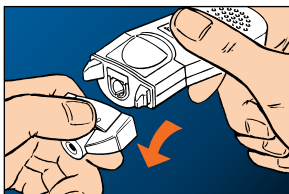
**Mark the Result:** Hold the button until “CONT” appears at the top of the display. Release the button and “CONT” begins flashing. Remove the Test Strip while “CONT” is flashing.



**Delete the Result:** Hold the button until “CONT” appears at the top of the display. Release the button and “CONT” begins flashing. Push the button again, “DEL” begins flashing above the date. Remove the Test Strip while “DEL” is flashing.

## What does blood glucose monitoring do for me?

Blood glucose levels change during the day due to medication, exercise, diet, insulins or hypoglycemics (oral agents) or possibly stress and illness. Blood glucose testing provides information that will help you understand the changes. This information can help you manage your diabetes to keep your blood sugar levels within your target range.



## Prepare for the Test:

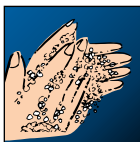
You will need a Microlet Lancing Device and Lancet to stick your finger, then cotton or tissue for wiping the finger after testing.

1. Wash your hands with warm, soapy water. Rinse and dry thoroughly.
2. Pull the endcap from the Microlet Device.
3. Push Microlet Lancet all the way in.
4. Twist off Lancet cap.
5. Snap the endcap back on.

See Microlet package insert for more details on how to use the Microlet Device.

## Take the Test:

### You need a Meter and Test Strip.



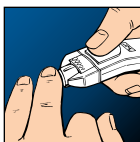
1. After washing your hands with warm soapy water and drying thoroughly, open a foil packet and remove the Test Strip.



2. With the Meter off, hold the round end and insert the Test Strip fully into the Meter. You will hear a beep.



After a full display, the Code Number (F#) and previous test result begin flashing alternately.



3. Press Microlet firmly against puncture site and push button to release. Form a small, round drop of blood.



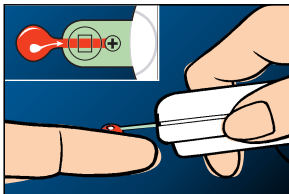
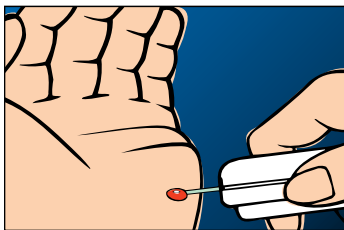
## Note: Multiple Site Testing

Consult with your healthcare professional prior to testing from a site other than your fingertips.

Blood glucose testing results from sites other than your fingertip could be significantly different. These differences may vary from individual to individual, and are physiological differences caused by factors such as food intake, health state and medication being used.

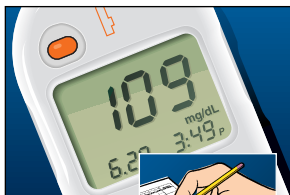
If you perform testing other than from a fingertip:

- A. Select a soft, fleshy area of skin that is free from hair and visible veins.
- B. Wash the puncture site with soap and warm water. Rinse and dry thoroughly. This ensures cleanliness and increases blood flow to the puncture site.
- C. After you have determined the proper depth of your selected site, set the lancing device for that depth of puncture. Firmly press the lancing device against the skin at the selected lancing site, then press the button to lance the skin. When a drop of blood forms on the surface of your skin, bring the meter and test strip up to touch the drop.



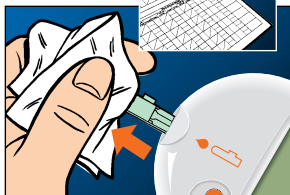
4. Touch and hold the TEST END (tip) of the Test Strip to the drop of blood until the Meter beeps. The Test Strip is filled, and the timer begins counting down from 29 seconds.

## Test Results:



After 29 seconds, your test result is displayed. Do not remove strip until results are displayed.

Record the test result/date in your Clinilog Diary.\*



Remove the Test Strip. The Meter turns off and the test result is stored.

**\*If you do not want to store the test result—before removing Test Strip**, press the button and hold until "CONT" appears. Release the button and "CONT" begins flashing. Press the button again, "DEL" begins flashing. Remove the Test Strip while "DEL" is flashing.



Remember this: test result will display with "DEL" when stored test results are reviewed.

**NOTE:** If you do not remove the Test Strip, the Meter will turn off automatically after 3 minutes.

**CAUTION:** Dispose of the used Test Strip and Lancet carefully to prevent injury or contamination to others. You may use the empty foil packet to dispose of the Test Strip.

**DON'T FORGET—when using the Meter:**

- Insert the Check Strip, Code Strip or Test Strip with a firm motion until it comes to a full stop.
- The tab on the strip can no longer be seen if the Test Strip has been inserted fully into the Meter.
- The Meter turns off automatically after 3 minutes if strip is left in the Meter.
- The Code Number (F#) **appearing in the Display** must match the number appearing on the:
  - Code Strip
  - Code Strip packet
  - Back of Test Strip packet
- To mark your Control Test at the beginning or end of the test (before removing Test Strip from the Meter). The “marking” prevents the Control Test result from being averaged with the blood glucose test results.
- You can recall all stored test results, which includes Control Tests and deleted tests.

**DON'T FORGET—when using the Meter (cont.):**

- When the Meter memory is full and a new test result is entered, the oldest result is deleted (i.e., #1).
- Teach another person how to use the system, so you will have someone to help if you ever need assistance.


**DON'T FORGET—when using a Test Strip:**

- Always check the expiration date on the Test Strip foil packet or carton. If date is passed, replace with unexpired Test Strips.
- Use the Test Strip immediately after removing from the packet.
- To be sure the Test Strip fills, hold the TEST END of Test Strip **in the blood drop** until the beep.
- Test Strips cannot be reused.
- Remove the Test Strip from the Meter immediately after use.

## How to recall test results:

1. Press the button to turn Meter on. After a full display and year, the current date and time are displayed. The 14-day average then appears with "MEM" (memory) and "A" (average) in the lower left corner.

The average result displayed is the average of all blood test results

obtained within the last 14 days. A  display indicates no blood test results the last 14 days.



2. Press the button again for latest test result with date and time of test.

3. To review test results stored, press button repeatedly (once for each test result). Any readings marked as "CONT" or "DEL" are not included in the 14-day average. When all test results have been displayed, "End" appears.

4. Press button for two seconds to turn Meter off.

## How to delete test results:

If you wish to delete all test results, while "End" is displayed, insert any strip (do not remove). "ALL" and "dEL" display alternately.

**If you change your mind, you must remove the Test Strip before the Meter turns off. "ALL" and "dEL" display alternately 5 times before the Meter turns off.**

When the Meter turns off, all results are deleted.



- **Use WinGlucofacts™ XL Diabetes Management Software.**
- Your Meter can transfer test results to a computer where results can be electronically summarized in a logbook report, graph, or chart.
- To make use of this feature, you need special software and a connecting cable.
- For more information relating to this program, contact Bayer Customer Service:  
**1-800-348-8100 (U.S. only) or visit our website at [www.ascensia.com](http://www.ascensia.com) or [www.bayercaresdiabetes.com](http://www.bayercaresdiabetes.com)**



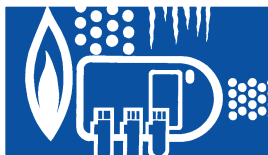
## Meter and Test Strip Care



- Wash hands and dry thoroughly before testing to keep the Meter and Test Strips free of oils and other contaminants.



- Handle the Meter carefully to avoid damaging the electronics or causing other malfunctions.



- Avoid exposing Meter and Test Strip to excessive humidity, heat, cold, dust, or dirt.



- The exterior of the Meter can be cleaned using a moist (not wet) lint-free tissue with a mild detergent or disinfectant solution.\* Wipe dry with lint-free tissue after cleaning.



- Store Meter in the case provided or a replacement case of your choosing whenever possible.

\*1 part bleach mixed with 9 parts water.

Healthcare professionals or persons using this system on multiple patients should be aware of the following and should follow the infection control procedure approved by their facility.

All products or objects which come in contact with human blood, even after cleaning, should be handled as if capable of transmitting viral diseases.

The user should follow the recommendations for prevention of blood-borne transmissible diseases in healthcare settings, as recommended for potentially infectious human blood specimens in National Committee for Clinical Laboratory Standards, *Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissues: Approved Guideline*. NCCLS Document M29-A [ISBN 1-56238-339-6] NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA, 1997. This document has complete information on the topic of user protection and can be used as background material for instruction.



# Meter and Test Strip Problems

See the possible solutions listed and if you need further assistance, contact Bayer Customer Service at:

**1-800-348-8100 (24 hours a day)**

| MESSAGE                                                                                                             | CAUSE                                                                                                                                                                                                                                                                            | SOLUTION                                                                                                                                                                                                                        |
|---------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| E-1 }<br>E-3 } display<br>E-4 }                                                                                     | Meter electronics failure.                                                                                                                                                                                                                                                       | Immediately contact the Customer Service Dept. 1-800-348-8100. <i>The Meter will no longer function.</i>                                                                                                                        |
| E-2 display                                                                                                         | Meter below or above operating temperature, 50°–104° F (10°–40° C).                                                                                                                                                                                                              | Allow Meter to come to room temperature before using. If E-2 continues to display, contact Customer Service Dept. (see above).                                                                                                  |
| Display goes blank after Test, Code or Check Strip is inserted into the Meter.                                      | <ol style="list-style-type: none"> <li>1. Strip is not fully inserted into the Meter.</li> <li>2. Batteries are not installed correctly.</li> <li>3. Batteries are dead.</li> <li>4. Too much time has passed since inserting the strip and the Meter has turned off.</li> </ol> | <ol style="list-style-type: none"> <li>1. Insert strip until tab is inside Meter.</li> <li>2. Install batteries correctly.</li> <li>3. Replace with <b>new</b> batteries.</li> <li>4. Remove and reinsert the strip.</li> </ol> |
| The <b>Code Number (F#)</b> displayed is different from the number printed on the Test Strip foil packet or carton. | <ol style="list-style-type: none"> <li>1. Wrong Code Strip used.</li> <li>2. Code Strip not inserted properly.</li> </ol>                                                                                                                                                        | <ol style="list-style-type: none"> <li>1. Use correct Code Strip. Discard incorrect one.</li> <li>2. Reinsert Code Strip carefully, but firmly.</li> </ol>                                                                      |
| Check Strip test result out-of-range.                                                                               | <ol style="list-style-type: none"> <li>1. Check Strip (Meter end) dirty or damaged.</li> <li>2. Meter electronics failure.</li> </ol>                                                                                                                                            | <ol style="list-style-type: none"> <li>1. Wipe Check Strip with clean dry tissue, and retest.</li> <li>2. Contact Customer Service Department.</li> </ol>                                                                       |

**MESSAGE****CAUSE****SOLUTION**

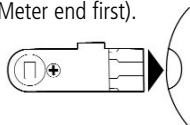
Meter fails to start countdown.

1. Blood applied wrong; see page 12.

1. Form a larger drop of blood or Control Solution and rerun test using a **new** Test Strip. Hold test end to sample until after the "beep".

2. Test Strip inserted incorrectly.

2. Insert Test Strip correctly (Meter end first).



3. Meter turned on before Test Strip inserted.

3. Press and hold button to turn Meter off. Remove Test Strip and reinsert to begin test procedure.

4. Sample is applied while full display is showing.

4. Wait for Code Number (F#) and last test result to begin flashing before applying sample to strip.



Some display segments do not appear.

Meter electronics or battery failure.

Replace batteries and if display is still incorrect, contact Customer Service Department.



Battery display.

Battery voltage low.

Replace batteries. See Section 1, page 4.

## Meter and Test Strip Problems

| MESSAGE                                                                                                                                            | CAUSE                                                                                                                                                                                                                                                       | SOLUTION                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>"Lo" display.</p> <p><b>CAUTION:</b><br/>Glucose levels below 50 mg/dL (2.8 mmol/L) may indicate a potentially serious medical condition.</p>   | <ol style="list-style-type: none"><li>1. The blood glucose value may be below 20 mg/dL (1.1 mmol/L).</li><li>2. Test Strip not filled completely.</li><li>3. Test Strip is defective or has deteriorated.</li><li>4. Wrong Code Number (F#) used.</li></ol> | <ol style="list-style-type: none"><li>1. Possible hypoglycemic condition (low blood sugar).<br/><b>Contact your physician or diabetes counselor about your condition.</b></li><li>2. Rerun test with <b>new</b> strip and apply sufficient sample to fill Test Strip. Hold test end to sample until after the "beep".</li><li>3. Rerun test using a new, unexpired Test Strip.</li><li>4. Use correct Code Strip provided with carton of Test Strips being used.</li></ol> |
| <p>"Hi" display.</p> <p><b>CAUTION:</b><br/>Glucose levels above 250 mg/dL (13.9 mmol/L) may indicate a potentially serious medical condition.</p> | <ol style="list-style-type: none"><li>1. The blood glucose value may be above 600 mg/dL (33.3 mmol/L).</li><li>2. Same as #3 above.</li></ol>                                                                                                               | <ol style="list-style-type: none"><li>1. Possible hyperglycemic condition (high blood sugar).<br/><b>Contact your physician or diabetes counselor about your condition.</b></li><li>2. Same as #3 above.</li></ol>                                                                                                                                                                                                                                                         |

**MESSAGE**

Blood glucose or Control Test results are inconsistent, or Control Test results are not within the specified range.

**CAUSE**

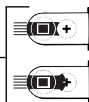
1. Not enough blood or Control Solution is drawn into the Test Strip.
2. Test Strips and/or Control Solution products have passed their expiration date.
3. Deteriorated Test Strip caused by heat or humidity.
4. Meter, Control Solution and/or Test Strip are not at room temperature when used.

**SOLUTION**

1. Rerun test with **new** Test Strip and apply sufficient sample to fill Test Strip. Hold TEST END to sample until after the "beep".
2. Obtain new Test Strips and/or Control Solution that are within their expiration date.
3. Run a Control Test using a **new** Test Strip. If results are still out of range, replace carton of Test Strips. See carton for proper storage instructions.
4. Allow time for Meter, Control Solution and/or Test Strips to come to room temperature before use.

**IMPORTANT:** To have accurate test results, sufficient sample to fill the reaction chamber is needed. The following drawings show how a Test Strip looks when filled and not filled.

**RIGHT**  
(filled)



**WRONG**  
(not filled)



**If attempts to correct a problem fail, please call our Customer Service Department. We have trained specialists to assist you.**

**1-800-348-8100**



**IMPORTANT:**

- Speak to a Customer Service Representative before returning your Meter for any reason. He/she will give you the information needed to get your problem handled correctly and efficiently.
- Have your Ascensia *ELITE*<sup>TM</sup> XL Meter, Ascensia *ELITE*<sup>TM</sup> Check Strip, and a box of Ascensia *ELITE*<sup>TM</sup> Test Strips (including the Code Strip) nearby when you phone. It would also be helpful to have a bottle of Ascensia *ELITE*<sup>TM</sup> Normal Control available.
- Fill out the **check list** on the following page before calling!

## Check List

1. The Meter serial number is: \_\_\_\_\_
2. The date and time the problem occurred was: \_\_\_\_\_
3. I tested with both the Check Strip and with the Ascensia *ELITE*<sup>TM</sup> Normal Control: Yes \_\_\_\_\_ No \_\_\_\_\_
  - The Check Strip result was: \_\_\_\_\_
  - The Normal Control result was: \_\_\_\_\_
4. The Normal Control Range listed on the end flap of the Test Strip carton is: \_\_\_\_\_ to \_\_\_\_\_
5. The Code Number being displayed on the Meter is:  
**F-** \_\_\_\_\_  
 The Code Number on the Code Strip and on the Test Strip foil packet currently being used is: **F-** \_\_\_\_\_
6. Please include the lot number and expiration date of the Test Strips and Controls currently being used. For the Test Strips, this information is printed on the carton as well as on the back of each foil packet. For the Controls, this information is printed on the bottle.

|                         | Test Strips | Control |
|-------------------------|-------------|---------|
| <b>Lot Number:</b>      | _____       | _____   |
| <b>Expiration Date:</b> | _____       | _____   |

## Limitations of the Procedure

**1. PRESERVATIVES:**

- **Fluoride** – Do not use fluoride as a preservative for blood specimens.
- **Iodoacetic acid** – Do not use iodoacetic acid as a preservative for blood specimens.

**2. ARTERIAL SPECIMEN:** Arterial specimens with  $pO_2$  of  $>200$  mmHg had a small bias (average of  $-6\%$ ) on the Ascensia *ELITE* in comparison to the laboratory method glucose results. The reference range for arterial  $pO_2$  is 80 to 110 mmHg (11.04 to 14.36 kPa).

**3. NEONATAL USE:** The **Ascensia *ELITE*™ XL System** is the only Ascensia *ELITE* System **qualified** for neonatal use. It is *intended for monitoring treatment* of hypoglycemia in neonates. The **Ascensia *ELITE* XL System** is *not intended for diagnosis* of neonates for hypoglycemia. Do not use any other Ascensia *ELITE*™ Blood Glucose Meter for neonatal testing.

**4. METABOLITES:** Reducing substances such as ascorbic acid and uric acid at normal blood concentrations do not significantly affect Ascensia *ELITE* XL blood glucose test results.

**5. HEMATOCRIT:** At normal glucose levels, Ascensia *ELITE* Test Strip results are not significantly affected by hematocrits in the range of 20% to 60%. At glucose levels above 300 mg/dL (16.7 mmol/L), hematocrit levels above 55% will cause lowered results. **For Neonatal Use:** At glucose levels between 20 mg/dL (1.1 mmol/L) and 120 mg/dL (6.7 mmol/L), Ascensia *ELITE* XL results are not significantly affected by hematocrit levels in the range of 20% to 70%.

**6. LIPEMIC SPECIMEN:** Cholesterol up to 500 mg/dL (13.0 mmol/L) or triglycerides up to 3000 mg/dL (33.9 mmol/L) do not significantly affect the results. Glucose values, however, in specimens beyond these levels should be interpreted with caution.

**CONTRAINDICATION (Bayer advises against):** Capillary blood glucose testing may not be clinically appropriate when peripheral blood flow is decreased. Shock, severe hypotension, hyperosmolar hyperglycemia and occurrence of severe dehydration are examples of clinical conditions which may adversely affect the measurement of glucose in peripheral blood.<sup>1</sup>

<sup>1</sup> Atkin S, Jaker MA, Chorost MI, Reddy S, Fingerstick Glucose Determination in Shock. *Annals of Internal Medicine* 1991, 114: 1020–24

# 14 SECTION Specifications

**Test Sample:** Whole blood

**Test Result:** Plasma/serum glucose

**Reaction Chamber**

**Sample Volume:** 2  $\mu$ L

**Measuring Range:** 20–600 mg/dL  
(1.1–33.3 mmol/L)

**Measuring Time:** 30 Seconds

**Calibration Curve:** Selected by use of the Code Strip

**Memory Feature:** Stores last 120 test results

**Temperature**

**Compensation:** Automatic compensation with built-in thermistor

**Battery Type:** 3-volt lithium batteries  
(DL or CR2032) – 2

**Battery Life:** Approximately 1000 Tests  
(1 year of average use)

**Operating**

**Temperature Range:** 50°–104° F (10°–40° C)

**Humidity:** 20–80% RH

**Dimensions:** 97.8 x 56 x 14.5 mm  
(3 $\frac{7}{8}$  x 2 $\frac{3}{16}$  x  $\frac{9}{16}$  in.)

**Weight:** Approximately 60g  
(2.1 ounces)

**Alarm:** “Beeps” whenever a Check Strip, Code Strip or Test Strip is inserted into the Meter, when the Test Strip is filled with blood or Control Solution, and when a test result appears in the display.



When calling or writing for supplies be sure to include the number with the name of the replacement part or accessory item.

## REPLACEMENT PARTS

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### Part Number\* Item

|          |                                                                                |
|----------|--------------------------------------------------------------------------------|
| 40030030 | 3-volt Lithium Battery (DL or CR2032) – 2<br>(Available at most Camera Stores) |
| 99C38839 | Ascensia <i>ELITE™ XL</i> User Guide                                           |
| 50184228 | Quick Reference Guide                                                          |
| 50062338 | Meter Battery Cover                                                            |
| 3437     | Interface Cable (WinGlucofacts™ XL)                                            |

**These parts are available in the United States from:**

**Bayer Corporation  
Customer Service Department  
Order Entry P. O. Box 2004  
Mishawaka, Indiana 46546**

**or call 1-800-348-8100 to order**

\*Part numbers are subject to change without notice

## ACCESSORY ITEMS

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### Product Code Number

### Item

|       |                                                                           |
|-------|---------------------------------------------------------------------------|
| 3870A | Ascensia <i>ELITE</i> ™ Test Strips – 50's<br>(Medicare patient use only) |
| 3871A | Ascensia <i>ELITE</i> ™ Test Strips – 50's<br>(mail order only)           |
| 3873A | Ascensia <i>ELITE</i> ™ Test Strips – 50's<br>(professional use only)     |
| 3911A | Ascensia <i>ELITE</i> ™ Test Strips – 25's                                |
| 3918A | Ascensia <i>ELITE</i> ™ Test Strips – 50's                                |
| 3942A | Ascensia <i>ELITE</i> ™ Test Strips – 100's                               |
| 3940A | Ascensia <i>ELITE</i> ™ Low and High Controls                             |
| 3972A | Ascensia <i>ELITE</i> ™ Normal Control                                    |
| 3416  | MICROLET® Vaculance® Lancing Device                                       |
| 6540B | MICROLET® Adjustable Lancing Device                                       |
| 6546B | MICROLET® Lancets (100's)                                                 |
| 6550B | MICROLET® Lancets (200's)                                                 |

### WinGlucofacts™ XL (English Only):

|      |                         |
|------|-------------------------|
| 3434 | (CD ROM)*               |
| 3435 | WINDOWS 95 DISKETTES*   |
| 3436 | WINDOWS 3.11 DISKETTES* |

\*Cable included

**Accessory items may be obtained from Diabetes Care Center, retail drug chain or other home healthcare distributors.**

**Manufacturer's Warranty:** Bayer Corporation ("Bayer") warrants to the original purchaser that this instrument will be free from defects in materials and workmanship for 5 years from the date of original purchase (except as noted below). During the stated 5-year period, Bayer shall, at no charge, replace a unit found to be defective with an equivalent or current version of the owner's model.

**Limitations of Warranty:** This warranty is subject to the following exceptions and limitations:

1. A 90-day warranty only will be extended for consumable parts and/or accessories.
2. This warranty is limited to replacement due to defects in parts or workmanship. Bayer shall not be required to replace any units which malfunction or are damaged due to abuse, accidents, alteration, misuse, neglect, maintenance by other than Bayer, or failure to operate the instrument in accordance with instructions. Further, Bayer assumes no liability for malfunction or damage to Bayer instruments caused by the use of reagents other than reagents (i.e., Ascensia *ELITE*<sup>TM</sup> Test Strips) manufactured or recommended by Bayer.
3. Bayer reserves the right to make changes in design of this instrument without obligation to incorporate such changes into previously manufactured instruments.
4. Bayer has no knowledge of the performance of the Ascensia *ELITE*<sup>TM</sup> XL Blood Glucose Meter when used with any Test Strips other than Ascensia *ELITE* Test Strips, and therefore makes no warranty of the performance of the Ascensia *ELITE* XL Meter when used with any Test Strips other than Ascensia *ELITE* Test Strips or when the Ascensia *ELITE* Test Strip is altered or modified in any manner.

BAYER MAKES NO OTHER EXPRESS WARRANTY FOR THIS PRODUCT. THE OPTION OF REPLACEMENT, DESCRIBED ABOVE, IS BAYER'S ONLY OBLIGATION UNDER THIS WARRANTY.

IN NO EVENT SHALL BAYER BE LIABLE FOR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF BAYER HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you. This warranty gives you specific legal rights and you may also have other rights which vary from state to state.

**For warranty service:** Purchaser must contact the Customer Service Department of Bayer Corporation, by calling toll free 1-800-348-8100, for assistance and/or instructions for obtaining service of this instrument.

Ascensia *ELITE*™, CLINILOG®, and MICROLET Vaculance® are registered trademarks of Bayer Corporation, Elkhart, Indiana.

WinGlucofacts™ is a trademark of Bayer Corporation, U.S.A.



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